

DOLEX FORTE- acetaminophen, aspirin, caffeine tablet

Pharmadel LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DOLEX FORTE (HPHARMA)

Drug Facts

Drug Facts

Active Ingredients and Purpose

<i>Active Ingredients</i>	<i>Purposes</i>
Acetaminophen 250 mg.....	Pain reliever
Aspirin 250 mg (NSAID*).....	Pain reliever
Caffeine 65 mg.....	Pain reliever aid

* nonsteroidal anti-inflammatory drug

Uses

Temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- toothache
- premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

Liver warning: This product contains **Acetaminophen**. Severe liver damage may occur if you take

- more than more than **8 caplets in 24 hours**, which is the maximum daily amount
- with other drugs containing **acetaminophen**
- 3 or more alcoholic drinks everyday while using this product

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (**NSAID**), which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks everyday while using this product
- take more or for a longer time than directed

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally a rapid heartbeat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin, or any other pain reliever/fever reducer
- with any other drug containing **acetaminophen** (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking

- a prescription drug for:
- diabetes
- gout
- arthritis
- any other drug, or are under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- pain gets worse or lasts for more than 10 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding,

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

OVERDOSE WARNING:

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not use more than directed (See OVERDOSE WARNING)**
- **adults and children 12 years and over:** take two (2) caplets every 6 hours with glass of water. Do not exceed **8 caplets** in 24 hours
- **children under 12 years of age:** consult a doctor

Other information

- store between 20°-25°C (68°-77°F) in a dry place
- read all product information before using. Keep box for important information.

Inactive ingredients

corn starch, crospovidone, hypromellose, microcrystalline cellulose, povidone, propylene glycol, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide

Questions?

1-866-359-3478 (M-F) 9AM to 5PM EST or www.pharmadel.com

Principal Display Panel

DOLEX®

FORTE

EXTRA STRENGTH

Acetaminophen, Aspirin, Caffeine

Pain reliever/Pain reliever Aid

55758-019-24

NDC 55758-019-24

DOLEX®

FORTE

EXTRA FUERTE

- *Dolor de Cabeza*
- *Reduce la Fiebre*
- *Dolor de Cuerpo*



24 CAPLETS† †Capsule-Shaped Tablet



Comparara los ingredientes activos con Exedrin®**

Acetaminofén,
Aspirina (AINE), Cafeína

DOLEX®





- Headache
- Fever reducer
- Body aches



24 CAPLETAS† †Tableta-Forma de Cápsula

NDC 55758-019-24



Compare to the active ingredient in Exedrin®**

**Acetaminophen,
Aspirin (NSAID), Caffeine**



FORTE

EXTRA STRENGTH

Acetaminophen, Aspirin (NSAID), Caffeine

DOLEX FORTE

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55758-306
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

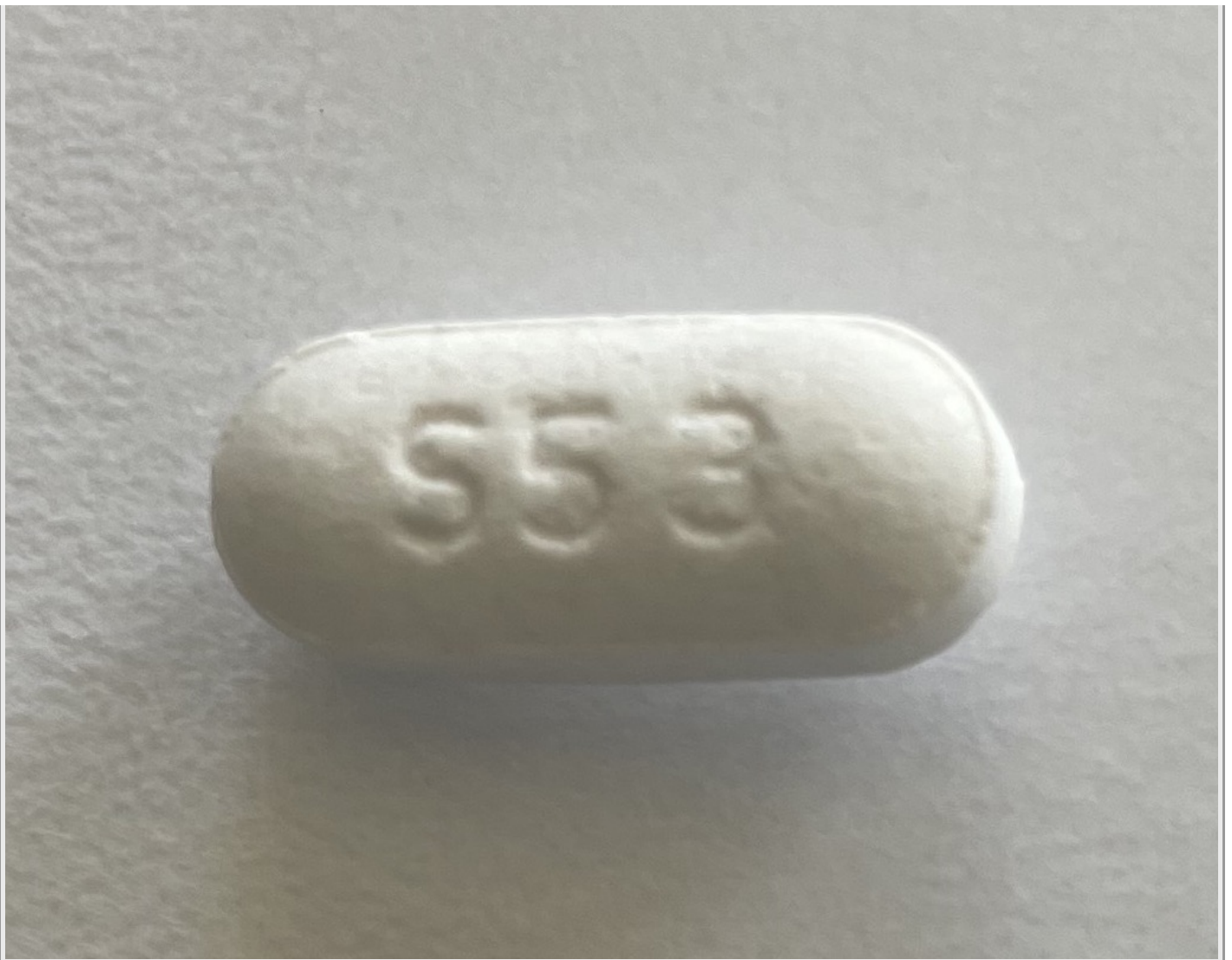
Ingredient Name	Strength
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CROSPVIDONE (UNII: 2S7830E561)	
POVIDONE (UNII: FZ989GH94E)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	CAPSULE ((Capsule-Shaped Tablet))	Size	18mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55758-306-24	1 in 1 CARTON	04/10/2023	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:55758-306-50	25 in 1 BOX	04/25/2023	
2	NDC:55758-306-02	2 in 1 PACKET; Type 0: Not a Combination Product		



Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	03/24/2013	

Labeler - Pharmadel LLC (030129680)

Revised: 4/2023

Pharmadel LLC